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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/696,699	10/29/2003	Bob G. Sanders	D6453CIP	7495

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EXAMINER	
CHOWDHURY, IQBAL HOSSAIN	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/696,699	SANDERS ET AL.	
	Examiner	Art Unit	
	Iqbal Chowdhury, Ph.D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-38* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, drawn to an isolated polynucleotide encoding a tocopherol associated protein p38, expression cassette and host cell, classified in class 435, subclass 325.

II. Claims 9, drawn to an isolated tocopherol associated protein p38, classified in class 530, subclass 350.

III. Claim 10, drawn to an antibody of tocopherol associated protein p38, classified in class 530, subclass 387.9.

IV. Claim 11-18, drawn to isolated polynucleotide encoding deletion mutants of tocopherol associated protein p46, expression cassette and host cell, classified in class 435, subclass 325.

V. Claim 19, drawn to an isolated polypeptide deletion mutant tocopherol associated protein p46, classified in class 530, subclass 350.

VI. Claim 20, drawn to an isolated deletion mutant tocopherol associated protein p38, classified in class 530, subclass 350.

VII. Claims 21-24, 29-34, drawn to a method for the treatment of neoplastic disease by administering a vector encoding tocopherol associated protein p38, classified in class 514, subclass 44.

VIII. Claims 21-24, 29-34, drawn to a method for the treatment of neoplastic disease by administering a vector encoding tocopherol associated protein p46, classified in class 514, subclass 44.

IX. Claims 21-23, 25-26, 28-30, drawn to a method for the treatment of autoimmune disease by administering a vector encoding tocopherol associated protein p38, classified in class 514, subclass 44.

X. Claims 21-23, 25-26, 28-30, drawn to a method for the treatment of autoimmune disease by administering a vector encoding tocopherol associated protein p46, classified in class 514, subclass 44.

XI. Claims 21-23, 25, 27, 29-30, drawn to a method for the treatment of viral disease by administering a vector encoding a tocopherol associated protein p38, classified in class 514, subclass 44.

XII. Claims 21-23, 25, 27, 29-30, drawn to a method for the treatment of viral disease by administering a vector encoding a tocopherol associated protein p46, classified in class 514, subclass 44.

XIII. Claims 35-38, drawn to an aerosolized liposome composition comprising a vector encoding tocopherol associated protein (p38 or p46 or deletion mutants), classified in class 424, subclass 450.

For each of inventions IV-XIII above, restriction to one of the following is also required under 35 USC121. Therefore, election is required of one of inventions IV-XIII and one of inventions (A) – (E).

(A). protein of SEQ ID No: 2 or a nucleic acid encoding SEQ ID No: 2.

(B). protein of SEQ ID No: 4 or a nucleic acid encoding SEQ ID No: 4.

(C). protein of SEQ ID No: 15 or a nucleic acid encoding SEQ ID No: 15.

(D). protein of SEQ ID No: 17 or a nucleic acid encoding SEQ ID No: 17.

(E). protein of SEQ ID No: 19 or a nucleic acid encoding SEQ ID No: 19.

The inventions are distinct, each from the other because of the following reasons:

2. The DNA of Group I, IV and the proteins of Group II, V-VI, antibody of Group III and a liposome composition of Group XIII, each comprise a chemically unrelated structure capable of separate manufacture, use and effect. The DNA comprises a nucleic acid sequence of Groups I and IV, and liposome composition of Group IX, the proteins of Group II, and V-VI, antibody of group III, each comprise unrelated amino acid sequences. The DNA has other utility besides encoding the proteins such hybridization or probe, the proteins can be made by another method such as isolation from natural sources or chemical synthesis and the proteins have other utility besides acting as an antigen to induce the antibodies such as for diacylglycerol (DAG) production.

3. Inventions I, IV and VII-XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid can be used for the hybridization and probe preparation.

4. Inventions polypeptide of Group II, V and VI, and antibody Group III are unrelated to the methods of Groups VII-XII as they are neither used nor made by the methods of Groups VII-XII as they have different modes of operation, different functions.

5. The methods of groups VII-XII are patentably distinct as they comprise unrelated steps, as different products and produce different effects.

6. The proteins of Group (A)-(E) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions represent structurally different polypeptides and polynucleotide encoding them. Therefore, where structural identity is required, such as for hybridization or expression or antibody binding, the different sequences have different effects.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37CFR 1.48b if one or more of the currently named inventors are no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under CFR 1.48 (b) and by the fee required under 37 CFR 1.17 (i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of

the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the imitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal H. Chowdhury whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).
Respectfully,

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